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JON SWANSON

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EXAMINER

TRAN, SUSAN T

ART UNIT

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1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Response to Arguments

Applicant's arguments filed 06/08/10 have been fully considered but they are not persuasive.

Applicant argues that Liversidge does not teach or suggest that the cellulosic surface stabilizer is integrated into a matrix or coats the HIV drug particles to control the release of the drug.

However, in response to applicant's arguments, the Examiner notes that Liversidge teaches the use of the same method to obtain the claimed nanoparticles. Liversidge teaches that the HIV drug particles is wet grinding with the cellulosic surfactant. In a different embodiment, dispersion medium containing HIV drug particles is mixed with a cellulosic surface stabilizer to form particles having an effective average particle size of less than about 1000 nm. See pages 14 and 33-34. It is of note that where the claimed and prior art products are *produced by identical or substantially identical processes*, a prima facie case of either anticipation has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Applicant argues that the Examiner's argument that the cellulosic surface stabilizer of Liversidge's composition reads on the rate-controlling polymer of the claimed invention is flawed. This is because the Examiner fails to articulate which component of Liversidge's composition would have taught the surface stabilizer of the

Art Unit: 1615

claimed invention, which is associated with the surface of the nanoparticulate drug particles. Applicants' claimed invention requires a surface stabilizer and a high molecular weight, rate controlling polymer. These two components are not the same.

However, Applicant's attention is called to the teachings in page 11, 2nd paragraph, where Liversidge teaches the use of other surface stabilizer in conjunction with the cellulosic surface stabilizer, including the claimed high molecular weight compound, such as polyvinyl pyrrolidone, poly(ethylene) oxide, and the like.

Accordingly, the rejection by Liversidge is maintained.

Applicant argues that neither Doi nor Sugimoto discloses a nanoparticulate active agent composition comprising a surface stabilizer associated with the surface of the active agent particles. In fact, a surface stabilizer is not required for either Doi's or Sugimoto's composition because the particle size of these prior-art compositions are large enough to maintain the stability of the composition. Neither reference discloses that a surface stabilizer is needed to prevent the particles of the active agent from agglomeration or aggregation.

However, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., neither reference discloses that a surface stabilizer is needed to prevent the particles of the active agent from agglomeration or aggregation) are not recited in the rejected claims. Although the claims are interpreted in light of the

Art Unit: 1615

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Doi teaches away from the claimed invention. Doi relates to a solid nifedipine preparation, which requires the specific combination of nifedipine with casein and one or more specific inorganic excipients. See column 3, lines 50-56. More specifically, Doi emphasizes that the crucial ingredients of the composition cannot be substituted, even by similar ingredients.

However, in response to Applicant's arguments, the Examiner notes that Doi teaches the claimed surface stabilizer, namely, casein. See for example, claim 37.

Applicant argues that the enteric high molecular substance taught in Doi is not coated as a thin film on granules or tablets.

However, the Examiner notes that although Doi teaches that the enteric high molecular substance is not coated as a thin film using organic solvent, Doi teaches using a double co-pulverized method to prevent rapid dissolution of nifedipine. Thus, the enteric high molecular substance taught in Doi can be coated as a powder or integrated into the granules.

In response to applicant's arguments with respect to Sugimoto, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the

Art Unit: 1615

test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Sugimoto is relied upon solely for the teachings that the claimed particle size is known in the art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. TRAN whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/S. TRAN/
Primary Examiner, Art Unit 1615

Application/Control Number: 09/337,675
Art Unit: 1615

Page 6